



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1140]

Enforcement Policy Regarding Federal Veterinarian-Client-Patient Relationship Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled “Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak,” which was issued in March 2020. FDA is withdrawing this guidance document in recognition that the conditions that created the need for the enforcement policy have evolved, such that the policy is no longer needed.

DATES: The withdrawal date is [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: William Flynn, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5704, AskCVM@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA’s commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID-19)¹ pandemic, in March 2020, the Agency published the guidance document GFI #269, “Enforcement Policy Regarding Federal

¹ The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19).

VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak,” recognizing the vital role veterinarians play in protecting public health. In accordance with the process announced by the Agency in the *Federal Register* on March 25, 2020 (85 FR 16949) for making COVID-19-related guidances available to the public, the notice of availability for the guidance published on May 12, 2020 (85 FR 28010).

When the COVID-19 public health emergency began in January 2020, FDA understood that veterinarians might face challenges affecting their ability to make on-premises examination of their patients. Given that the Federal veterinarian-client-patient relationship (VCPR) definition (21 CFR 530.3(i)) requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine. To facilitate veterinarians’ ability to utilize telemedicine to address animal health needs during the COVID-19 outbreak, FDA published GFI #269, stating that it intended to temporarily suspend enforcement of a portion of the Federal VCPR requirements. Specifically, FDA generally intended not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals (21 CFR part 530) and Veterinary Feed Directive Drugs (21 CFR 558.6).

FDA stated in the guidance that, given the temporary nature of this policy, we planned to reassess it periodically and provide revision or withdrawal of this guidance as necessary. The Agency acknowledges that the public health emergency declared by the Secretary of Health and Human Services for the COVID-19 pandemic continues to exist. However, the conditions that created the need for the temporary enforcement policy outlined in GFI #269 have evolved, such that the policy is no longer needed. After careful review of current industry practices with regard to on-premises animal examination and comments submitted to the public docket associated with the guidance, the Agency has determined the guidance document should be withdrawn.

Therefore, in accordance with 21 CFR 10.115(k), FDA is withdrawing the “Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak” guidance in its entirety.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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